AUG 2 6 2003

K022721

## 510(K) SUMMARY
**Uropower**

**I. Submitter:**

W.O.M. WORLD OF MEDICINE AG
Alte Poststraße 11
96337 Ludwigsstadt
Germany

**II. Device Names:**

| | | |
|---|---|---|
| 1. | Classification Name: | Uroflowmetry System |
| 2. | Common or Usual Name: | Uroflowmeter |
| 3. | Proprietary Name: | Uropower |

**III. Classification:**

Class II. This device is described in 21 C.F.R. § 876.1800. The product code for the device is EXY.

**IV. Predicate Devices:**

- **Ultracompact** (K894968) from Eutectic Electronics, Inc.

**V. Intended Use:**

The Uropower is a urine flow and volume measuring system intended for lay use to measure the urine volume and flow of men during the course of normal urination. The device is also intended to be used by health care professionals.

**VI. Device Description:**

The Uropower is a device intended to measure the urine flow and calculate the volume of males in order to identify micturition disturbances. It is designed to be used by health care professionals and by laymen. The system consists of a base unit, a urinal-flow-transducer and various mount elements. Due to its construction the transducer can be installed in a urinal. The user is guided by instructions shown on the LCD display of the base unit. The urinal flow transducer measures the flow of the urine in accordance with the through-flow-principle, a volume per time measurement. The base unit calculates the total voided volume, maximum flow rate, mean flow rate, total measuring time, flow time, time to max. flow and medical data like the flow index. All parameters are printed on a thermo card.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2003

W.O.M. World of Medicine AG
c/o Ms. Susan Raab
Official Correspondent
368 N. Asaph Street
ALEXANDRIA VA 22314

Re: K022721
Trade/Device Name: Uropower™
Regulation Number: 21 CFR §876.1800
Regulation Name: Urine flow or volume measuring system
Regulatory Class: II
Product Code: 78 EXY
Dated: July 28, 2003
Received: July 30, 2003

Dear Ms. Raab:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K022721

# STATEMENT OF INDICATIONS FOR USE

APPLICANT: W.O.M. WORLD OF MEDICINE AG

510(K) NUMBER (if known): K022721

DEVICE NAME: Uropower

INDICATIONS FOR USE:

The Uropower is a urine flow and volume measuring system intended for lay use to measure the urine flow and volume of men during the course of normal urination. The device is also intended to be used by health care professionals.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

*Over-The-Counter Use* ✓

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022721